

Remarks

Amendments to the Claims

Independent claim 1 has been amended to recite “a soluble form of a human CD8 molecule which has no specific antigen-binding capability other than that of native CD8.” The amendment is supported throughout the specification; *e.g.*, page 4, lines 7-15; page 5, lines 5-18; page 10, lines 21-27. Claim 1 also is amended to recite SEQ ID NO:24 (an amino acid sequence) rather than SEQ ID NO:23 (a nucleic acid sequence); this amendment merely corrects an obvious clerical error.

New claim 29 is supported, *inter alia*, by Example 10.

The amendments add no new matter.

Rejection of Claims 1, 5, 24, 25, and 27 Under 35 U.S.C. § 112 ¶ 2

Claims 1, 5, 24, 25, and 27 stand rejected under 35 U.S.C. § 112 ¶ 1 as indefinite because SEQ ID NO: 23 is a nucleic acid sequence. Claim 24 has been canceled. Independent claim has been amended to recite SEQ ID NO:24, which is an amino acid sequence. Please withdraw the rejection.

Rejection of Claims 1, 5, 24, 25, and 27 Under 35 U.S.C. § 112 ¶ 1

Claims 1, 5, 24, 25, and 27 stand rejected under 35 U.S.C. § 112 ¶ 1. The Final Office Action contends that the subject matter recited in claim 24 and in claim 1, parts (vi) and (vii) are insufficiently described. To advance prosecution, claim 24 has been canceled, and parts (vi) and (vii) of claim 1 have been deleted. Please withdraw the rejection.

Rejection of Claims 1, 5, 25, and 27 Under 35 U.S.C. § 102(b)

Claims 1, 5, 25, and 27 stand rejected under 35 U.S.C. § 102(b) as anticipated by any of three Tykocinski patents,¹ as evidenced by Boursier.² Applicants respectfully traverse the rejection.

A reference cited under 35 U.S.C. § 102 must expressly or inherently describe each element set forth in the rejected claim. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Independent claim 1 as amended recites “contacting the target cell with a soluble form of a human CD8 molecule which has no specific antigen-binding capability other than that of native CD8.” The Tykocinski patents teach immunosuppression using CD8:ligand conjugates, *i.e.*, conjugates which have binding capability in addition to that of native CD8. For example, see Tykocinski ‘867 at col. 11, line 66 to col. 12, line 12:

The CD8-mediated inhibitory effect is contingent upon the simultaneous copresentation of a molecular signal that normally, in the absence of CD8, contributes to cellular activation. This second signal can be provided by a second molecule noncovalently associated with CD8, by virtue of its presence on the same biomembrane with CD8, or covalently associated with CD8 in an artificial CD8:ligand conjugate. The nature of the second, noncovalently or covalently, associated ligand dictates the nature of the target cell to be inhibited. Specific T cells can be inhibited by CD8 in association with allogeneic MHC or an MHC:NAP complex. Other specific target cells can be selectively inhibited using other CD8:ligand combinations as cited (*vide supra*).

There is no explicit or inherent teaching in any of the Tykocinski patents of using for immunosuppression a soluble CD8 dimer having “no specific antigen-binding capability other than that of native CD8” as recited in amended claim 1. Boursier provides no evidence to the

¹ U.S. Patent 5,242,687; U.S. Patent 5,601,828; and U.S. Patent 5,623,056.

² *J. Biol. Chem.* 268(3), 2013-20, 1993.

contrary. Thus, the Tykocinski patents (with or without Boursier) do not anticipate claims 1, 5, 25, and 27.

Please withdraw the rejection.

Respectfully submitted,
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